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REMARKS

Claims 1-45 are pending. By the above amendment, claim 1 has been amended and claim 45 has been added.

Support for the amendment to claim 1 can be found, for example, in dependent claims 2, 3, 8, 9 and 10. Support for a hydrogel can be found, for example, in paragraph 0041. Support for the specific hydrogels of new claim 45 can be found, for example, in paragraph 0039.

Claim Rejection under 35 USC §102(b) and 103(a)

Claims 1-8, 12-29, 33-34, 36-37, and 39-44 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. 5,629,077 (Turnlund), whereas claims 9-11, 30-32, 35 and 38 are rejected under 35 U.S.C. 103(a) as obvious over Turnlund. Applicant respectfully traverses these rejections and their supporting remarks.

For example, independent claim 1 is directed to an implantable or insertable medical device comprising a biodegradable inner material and a biodegradable covering material at least partially covering the inner material, which, after insertion or implantation into a patient, becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. The biodegradable inner material is selected from (a) a polymeric material that is more flexible than the covering material, (b) a hydrogel material that becomes flexible upon contact with body fluids, (c) a metallic material, and (d) a ceramic material.

As indicated in paragraphs 0031, 0034, 0035 and 0045 of the as-filed specification, even where the inner material and the covering material are both biodegradable and the medical device will eventually be completely biodegraded, prior to complete biodegradation, the device will nevertheless undergo a controlled change in its mechanical properties, rendering it increasingly biomechanically compatible, i.e., compliant, with the surrounding and contacting tissue. Consequently, the medical devices of the present invention provide a decreased risk of tissue damage caused by lack of biomechanical compatibility and/or the possibility of fragmentation. For example, in the case of a coronary vascular stent in accordance with the present invention,

because restenosis is believed to be associated with the lack of biomechanical compatibility between the stent and the surrounding and contacting tissue, such a stent provides a decreased risk of restenosis. Ways of increasing the biomechanical compatibility of the device include the following: (a) inner materials can be used that are more flexible that the covering material at the time the device is introduced into the subject , (b) inner materials such as hydrogels are used that become more flexible upon contact with the subject's biological fluids, and (c) in the case of high modulus materials such as metals and ceramics, inner materials can be used which have a thinner gauge than would be used in devices that do not include the biodegradable covering material, which provides added overall mechanical strength and rigidity to the device.

Such an invention is neither taught nor suggested by Turnlund, which describes a biodegradable mesh and film stent, for use in blood vessels, which is formed of a sheet of a composite mesh material formed of high strength polymer fibers (i.e., the mesh) formed of a first biodegradable polymer, which are bonded together with a second biodegradable adhesive polymer, and laminated on one or both sides with a film of a third biodegradable polymer. See Turnlund abstract.

On the other hand, the inner material of claim 1 is selected from (a) a polymeric material that is more flexible than the covering material, (b) a hydrogel material that becomes flexible upon contact with body fluids, (c) a metallic material, and (d) a ceramic material.

With respect to claim element (a), in contrast to stiffening the device with the covering material as claimed, Turnlund structurally supports the stent with the inner material, specifically, with a mesh of high-strength, high modulus (i.e., high stiffness) fibers. For example, Turnlund's preferred material for use as the fiber mesh is PGA (see col. 5, line 25), which has a published modulus of 7.0 GPa (see attached article entitled "Synthetic Biodegradable Polymers as Medical Devices"). Modulus is a measure of the stiffness of a material. For the adhesive the preferred materials are PCL, which has a published modulus of 0.4 GPa, DL-PLA, which has a published modulus of 1.9 GPa, and a combination of PCL and L-PLA (see col. 5, lines 35-40). For the film, the preferred polymers are DL-PLA, which has a published modulus of 1.9 GPa, and L-PLA, which has a published modulus of 2.7 GPa (see col. 6, lines 29-32). Hence, in contrast to element (a) of claim 1, in which the inner polymeric material is more flexible than the covering

material, in Turnlund, the inner polymeric material is the stiffest material, and in fact has a modulus that is more that two and a half times the modulus of the outer film.

With respect to claim element (b), Turnlund neither teaches nor suggests an inner hydrogel material that becomes flexible upon contact with body fluids. For example, hydrogels are not known as lending themselves for use as adhesives (e.g., they are commonly lubricious) or as structural materials (e.g., they are quit flexible).

With respect to claim elements (c) and (d), Turnlund neither teaches nor suggests ceramic or metallic materials, but rather is directed to biodegradable polymers.

For at least these reasons, it is respectfully submitted that claim 1 is patentable over Turnlund. Claims 2-21 and 45 depend upon claim 1 and are therefore patentable over Turnlund for at least the same reasons as is claim 1.

Claim 22 is directed to an implantable or insertable medical device comprising a non-biodegradable inner material and a biodegradable covering material at least partially covering the inner material, wherein after insertion or implantation into a patient, the medical device becomes decreasingly rigid and increasingly biomechanically compatible with body tissue in contact with the device over time. Hence, in contrast to Turnlund, in which all of the materials are biodegradable, claim 22 is directed to a medical device that comprises a non-biodegradable inner material.

For at least this reason, it is respectfully submitted that claim 22 is patentable over Turnlund. Claims 23-44 depend upon claim 22 and are therefore patentable over Turnlund for at least the same reasons as claim 22.

In view of the above, reconsideration and withdrawal of the rejection of claims 1-44 as being either anticipated by Turnlund under 35 U.S.C. 102(b) or obvious over Turnlund under 35 U.S.C. 103(a) are respectfully requested.

CONCLUSION

Applicant submits all pending claims are in condition for allowance, early notification of which is earnestly solicited. Should the Examiner be of the view that an interview would expedite consideration of this Amendment or of the application at large, request is made that the Examiner telephone the Applicant's attorney at (703) 433-0510 in order that any outstanding issues be resolved.

FEES

If there are any fees due and owing in respect to this amendment, the Examiner is authorized to charge such fees to deposit account number 50-1047.

Respectfully submitted,

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I hereby certify that this document and any document referenced herein is being sent to the United States Patent and Trademark office via Facsimile to: 703-872-9302 on Oct. 1, 2004.

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